

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING  
PHARMACY, INC. PRODUCTS LIABILITY  
LITIGATION

MDL No. 2419

THIS DOCUMENT RELATES TO:

Dkt. No. 1:13-md-2419 (RWZ)

All Suits Naming St. Thomas Outpatient  
Neurosurgical Center

**MEMORANDUM IN SUPPORT OF PLAINTIFFS’  
STEERING COMMITTEE’S MOTION TO  
QUASH SUBPOENAS AND FOR PROTECTIVE ORDER**

The Plaintiffs’ Steering Committee (“PSC”) moves, pursuant to Fed. R. Civ. P. 45 and 26(b)(2)(C), for a protective order to quash three third-party subpoenas directed by STOPNC<sup>1</sup> to previous employers and affiliates of PSC common expert Dr. David A. Kessler. STOPNC served subpoenas dated March 25, 2016 to three non-parties: the Yale School of Medicine, the University of California, San Francisco School of Medicine, and the American Board of Pediatrics. Dkt. Nos. 2794-1, 2794-2, 2794-3. STOPNC filed the notice of issuance and service of subpoenas on April 11, 2016. Dkt. No. 2794.

The subpoenas exceed the bounds of Rule 26 because they seek information that is irrelevant, and that is personal and confidential. Dr. Kessler’s offer of employment from Yale, his hospital admitting privileges, and his pediatrics board certification are all personal information irrelevant to the basis and substance of his opinions in this case. Those opinions are

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<sup>1</sup> STOPNC refers to a group of defendants: Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; and Vaughan Allen MD.

based on his experience as Commissioner of the FDA from 1990-1997, and on his review of relevant documents. The subpoenas also violate Rule 45 because STOPNC did not provide notice to the PSC before serving, and did not specify a place for the production of documents. The Court should issue a protective order quashing the three subpoenas.

## **I. Background**

### **A. Dr. Kessler**

Plaintiffs have retained David A. Kessler, M.D., as a testifying expert. *See* Ex. A (Kessler Rep.); Ex. B. (Kessler C.V.). Dr. Kessler was appointed by President George H.W. Bush in 1990 to be the Commissioner of the United States Food and Drug Administration. He served in that position, under Presidents Bush and Clinton, until February 1997. In that role, Dr. Kessler had ultimate responsibility for implementing and enforcing the United States Food, Drug, and Cosmetic Act, oversaw five Centers within FDA, created an Office of Criminal Investigation to investigate suspected criminal violations of the Act and FDA regulations, and testified before a Congressional Committee regarding the risks of compounded pharmaceutical products.

Plaintiffs retained Dr. Kessler to provide testimony regarding FDA's policies concerning the traditional role of pharmaceutical compounding, as opposed to non-traditional pharmaceutical compounding; the risks of non-traditional pharmaceutical compounding that were considered and communications made by FDA regarding such risks, the history of FDA's efforts to regulate the nontraditional compounding pharmaceutical industry, and the industry's resistance to such efforts; limitations on FDA's ability and resources to regulate nontraditional compounding; FDA and industry standards as to valid prescribing practices for compounded

pharmaceuticals; and the role of a formulary system in promoting patient safety.

Based on his experience as FDA Commissioner, and on his review of relevant documents, Dr. Kessler reached several conclusions relevant to the issues in this case:

- Non-traditional compounded drugs pose a health risk for patients.
- Even with FDA and state oversight of compounding pharmacies, practitioners and providers have the responsibility to follow basic safety practices.
- Making up names to obtain compounded drugs removes the FDA safeguard that physicians make an individual risk benefit decision for a particular patient at a particular point in time when prescribing compounded drugs.
- A formulary system identifies those drugs that are most medically appropriate and cost-effective, and following a written formulary is important to patient safety. Compounded methylprednisolone acetate was not listed in the St. Thomas Outpatient Neurosurgical Center formulary.

After Dr. Kessler left the FDA, he served as the Dean of the Yale University School of Medicine from 1997 to 2003. He then worked as the Dean of the School of Medicine, Vice Chancellor of Medical Affairs, and Professor of Pediatrics, as well as of Epidemiology and Biostatistics, all at the University of California, San Francisco from 2003 to the present. Dr. Kessler was an attending physician at the UCSF Medical Center for the first three months of 2003 and has not been an attending physician since.

**B. Procedural History**

STOPNC issued subpoenas, dated March 25, 2016, to three non-party entities:

- The subpoena to the American Board of Pediatrics demanded documents “addressing the date of Board of Pediatrics Certification by [Dr. Kessler], the dates of all re-certifications by [Dr. Kessler], and expiration of [Dr. Kessler’s] board certification by the American Board of Pediatrics. Dkt. No. 2794-1.
- The subpoena to the Yale School of Medicine demanded documents “reflecting the date and content of [Dr. Kessler’s] offer of employment as the Dean of the

Yale School of Medicine, and the date of Dr. Kessler's acceptance of the offer. Dkt. No. 2794-2.

- The subpoena to the UCSF School of Medicine demanded documents "reflecting (1) the date of expiration of [Dr. Kessler's] admitting privileges at any hospital; and (2) the last date on which [Dr. Kessler] had a physician/patient relationship with any patient." Dkt. No. 2794-3.

The subpoenas each command that the third parties produce documents at a location "[t]o be determined" by each of them. On April 11, 2016, STOPNC filed a notice of issuance and service of subpoena. Dkt. No. 2794. The notice stated that the subpoenas were inadvertently served before the notice was provided to other parties in the litigation, as required by Fed. R. Civ. P. 45.

## **II. Argument**

A subpoena issued to a non-party pursuant to Rule 45 is subject to Rule 26(b)(1)'s overriding requirement of relevance. *E.E.O.C. v. Texas Roadhouse, Inc.*, 303 F.R.D. 1, 2-3 (D. Mass 2014); *see also* Dkt. No. 572, at 7 ("A Rule 45 subpoena must fall within the scope of proper discovery under Fed. R. Civ. P. 26(b)(1)."). "Under Rule 26, the trial court is required to balance the burden of proposed discovery against the likely benefit." *Gill v. Gulfstream Park Racing Ass'n, Inc.*, 399 F.3d 391, 400 (1st Cir. 2005). "The Court thus engages in a balancing test, weighing the defendants' need for this information, the availability of other means of obtaining it, and the burden placed on the claimants by the subpoenas." *Texas Roadhouse*, 303 F.R.D. at 2.

First, the information sought is not "relevant to the claim or defense of any party." Dkt. No. 572, at 7. Dr. Kessler's opinions are based on his experience as a government regulator and

policymaker, corresponding expertise in the practices and regulation of the pharmaceutical industry, and review of the relevant documents in this case. His qualifications and opinions have nothing to do with his offer and acceptance of employment at the Yale School of Medicine after his tenure at the FDA ended. Similarly, his expertise on non-traditional compounded drugs, and the responsibilities of providers in dealing with compounding pharmacies, do not stem from his experience as a practicing pediatrician. The details of his admitting privileges when he served as the Dean of UCSF School of Medicine, and related pediatric certifications are therefore immaterial.

Second, in addition to being wholly without a legitimate basis, the requests are unduly burdensome because they seek Dr. Kessler's protected personal information. *See Gill*, 399 F.3d at 402 (explaining that interests in privacy should be taken into account in the Rule 26 analysis); *see also Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 35 n.21 (1984) ("Although [Rule 26(c)] contains no specific reference to privacy or to other rights or interests that may be implicated, such matters are implicit in the broad purpose and language of the Rule.").

The information sought from Yale is contained in Dr. Kessler's personnel files, which "courts have noted contain private information." *Texas Roadhouse*, 303 F.R.D. at 2-3; *see also Whittingham v. Amherst Coll.*, 164 F.R.D. 124, 127-28 (D. Mass 1995) (explaining that personnel files are confidential and that discovery concerning them should be limited); *Chamberlain v. Farmington Sav. Bank*, No. 3:06-cv-01437, 2007 WL 2786421, at \*1 (D. Conn. Sept. 25, 2007 (explaining that a party "clearly has a personal right with respect to the information contained in his employment records"). Indeed, under Connecticut law, the information STOPNC seeks from Yale ordinarily may not be disclosed without Dr. Kessler's

consent. *See* Conn. Gen. Stat. § 31-128f. Dr. Kessler's admitting privileges and Board certification, although they may or may not be contained in formal personnel files, similarly concern private employment information.

Finally, all three subpoenas also violate Rule 45's procedural requirements. Where, as here, a subpoena "commands production of documents," then before it is served, a notice must be served on each party. Fed. R. Civ. P. 45(b)(1); *see also* Dkt. No. 572, at 10. STOPNC did not serve prior notice, and instead filed a belated notice more than two weeks after the date of the subpoenas. Additionally, Rule 45(a)(1)(A)(iii) requires that a subpoena direct document production "at a specified time and place." Here, all three subpoenas direct documents be produced at a place "[t]o be determined" but each of the third parties. That plainly does not set out a "specified" place.

### **III. CONCLUSION**

The three non-party subpoenas served by STOPNC are procedurally flawed and substantively unjustified. The Court should issue a protective order quashing all three subpoenas.

Dated: April 18, 2016

Respectfully submitted,

/s/ Mark P. Chalos

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*Plaintiffs' Steering Committee*



**CERTIFICATE OF SERVICE**

I, Mark P. Chalos, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: April 18, 2016

/s/ Mark P. Chalos

Mark P. Chalos